

Bleeding, Thrombosis, Embolization, and Other Complications

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TCT-546

Timing of Access Site Bleeding After Transfemoral Coronary Intervention

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Background: Same day discharge after elective PCI is rare in the United States, partly due to concerns over access site complications associated with transfemoral intervention (TFI). The timing of access site bleeding after TFI in the modern era of PCI is unclear. **Methods:** 1525 consecutive patients undergoing elective PCI between January 2008 to May 2012 at a community hospital, were prospectively followed throughout their hospitalization. Patients undergoing radial procedures, on warfarin, and those receiving intra-aortic balloon pump were excluded. "Early" access site bleed was defined as any bleeding that occurred within 6 hours of completion of procedure, and "late" bleeds were defined as those occurring after 6 hours. Demographic, procedural and laboratory parameters were compared between patients who had bleeding versus those who did not (Table 1).

Results: 78 patients (5.1%) developed access site bleeding. 70 events (90%) occurred less than 6 hours after the procedure and 8 events (10%), after 6 hours. Median time to bleeding was 30 minutes in the "early" group, and 7.75 hours in the "late" group, and 1 hour for the entire cohort. Results of univariate analysis are shown in Table 1, with female gender and glycoprotein 2b/3a inhibitors identified as significant predictors of access site bleeding. Multivariate analysis did not identify any predictors of late bleeds.

Conclusions: Majority of the access site bleeding events after transfemoral PCI occur within six hours after the index procedure. Although these findings have favorable implications on same day discharge strategy, a larger study to identify predictors of late bleeds is needed.

	Access site bleed (N)	No access site bleed (N)	P-value
Female Gender	49/78 (62.8%)	514/1447 (35.5%)	0.001
Diabetes	27/78 (34.6%)	536/1447 (37.04%)	0.38
Hypertension	63/78 (80.76%)	1133/1447 (78.29%)	0.36
CABG	10/78 (12.82%)	228/1447 (15.75%)	0.30
GP2b3a	14/78 (17.94%)	157/144 (10.9%)	0.046
Bivalirudin	40/78 (51.28%)	861/1447 (59.5%)	0.47
Age	67.8 ± 11.9	66.2 ± 12.4	0.265
Height (Inches)	67.2 ± 4.3	67.1 ± 4.3	0.929
Weight (lbs)	192.1 ± 42.4	193.2 ± 46.8	0.826
Baseline Hemoglobin	13.3 ± 1.9	13.3 ± 1.9	0.691

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Ischemic stroke associated with left cardiac catheterization: the importance of modifiable and no modifiable risks factors

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Background: Stroke after left cardiac catheterization is infrequent but it represents the most debilitating complication from the patient perspective. Whereas the overall rate of adverse events declined over the last decades, the incidence of periprocedural stroke has remained unchanged. Ischemic stroke represents a high majority of symptomatic strokes and the potential mechanisms underlying these events include thrombus or air embolization, iatrogenic arterial dissection, hypotension and embolization debris of atheroma from the aortic wall. Given the devastating consequence, we sought to identify incidence, in-hospital outcomes and all modifiable and no modifiable risks factors of this adverse event in a high volume center.

Methods: Our retrospective study included all patients experiencing periprocedural ischemic stroke among 24500 patients who underwent left cardiac catheterization between January 2003 and October 2010. The stroke group were compared with a case group control of 500 individuals randomized from the initial source population.

Results: Ischemic cardiovascular events occurred in 46 patients (0.19% of procedures) and included transient ischemic attack (TIA) in 16 cases and stroke in 30 cases. Hospital

stay was significantly prolonged (12.4 vs 8.2 days $p < 0.001$) and the in-hospital mortality was higher (8.7% vs 0.6% $p < 0.001$) in stroke group. On multivariate analysis, diabetes mellitus (adjusted odds ratio (OR) 3.6; 95% confidence interval (CI) 1.7 to 7.7; $p < 0.001$); chronic renal dysfunction (OR 2.4, 95% CI 1.1-5.4; $p < 0.001$), known cerebrovascular disease (OR 7.3, 95% CI 3-17.8; $p < 0.001$) and recent congestive heart failure (OR 2.6, 95% CI 1.1-6; $p < 0.001$) were independent predictors for stroke. The independent modifiable predictive factors were represented by left ventricular angiography (OR 5.6, 95% CI 2.2-13.8; $p < 0.001$), emergent cardiac catheterization (OR 4.5, 95% CI 1.8-11.2; $p < 0.01$) and low operator volume (OR 2.7, 95% CI 1.3-3.8; $p < 0.01$).

Conclusions: A really careful procedural planning taking account patients, procedural risk factors and operator experience might still actually decrease the incidence of this devastating complication.

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Long-Term Follow-Up After Percutaneous Coronary Intervention With Polytetrafluoroethylene-Covered SYMBIOT Stents Compared To Bare Metal Stents, With And Without FilterWire Embolic Protection, In Diseased Saphenous Vein Grafts. The STROMBOLI Trial

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Background: The long-term clinical outcome of bulky covered stents in the percutaneous treatment of diseased saphenous vein graft (SVG) has been disappointing. However, the single self-expanding polytetrafluoroethylene (PTFE)-covered Symbiot stent with a unique profile, has not been evaluated and may present advantages that translate into superior long-term clinical outcomes. This study evaluated the safety, effectiveness and clinical outcome of the SymbiotTM covered stent system (Boston Scientific, Natick, Mass.) and FilterWireTM EX (Boston Scientific, Natick, Mass.) versus bare metal stents (BMS) in SVG intervention.

Methods: Between January 2003 and August 2005, 90 patients with degenerative SVG lesions were prospectively randomized at 6 study sites to Symbiot implantation (n=30), BMS with FilterWire as embolic protection device (EPD, n=30), or BMS without EPD (control group, n=30). The primary endpoint was reduction in peri-procedural cardiac enzyme rise. The major secondary endpoints were in-hospital, 6 month and long-term target vessel failure (TVF) rates, defined as the cumulative of death, myocardial infarction and clinically-driven target lesion revascularization.

Results: There was no significant reduction in median [IQR] post-procedural troponin-I rise in the Symbiot group compared to the FilterWire or the Control group (0.08 [0-1.40] $\mu\text{g/L}$; 0.06 [0-0.28] $\mu\text{g/L}$; and 0.04 [0-0.31] $\mu\text{g/L}$, $p=0.58$). At 7.4 ± 1.3 (mean ± SD) years of follow-up (Table), there were numerically less deaths in the Symbiot group, although this did not reach statistical significance ($p=0.20$). There was no significant difference in TVF-free survival between the treatment groups ($p=0.98$).

Clinical Events at Longest Available Clinical Follow-Up Values are mean ±SD and event rates are Kaplan-Meier estimates (number of events (%))

	Symbiot Group (n = 30)	FilterWire group (n = 30)	Control Group (n = 30)	p Value
Long-Term Follow-Up (years)	7.3 ± 1.6	7.6 ± 0.9	7.4 ± 1.6	0.68
Death, all cause				
In-hospital	1 (3)	1 (3)	-	0.60
6 Months	3 (10)	2 (7)	1 (3)	0.58
Long-Term	6 (20)	13 (43)	11 (37)	0.20
Myocardial infarction				
In-hospital	2 (7)	1 (3)	1 (3)	0.76
6 Months	2 (7)	2 (7)	2 (7)	1.00
Long-Term	7 (23)	5 (17)	7 (23)	0.69
Target lesion revascularization				
In-hospital	1 (3)	-	-	0.37
6 Months	3 (10)	2 (7)	1 (3)	0.59
Long-Term	8 (27)	5 (17)	10 (33)	0.32
Target vessel failure				
In-hospital	3 (10)	1 (3)	1 (3)	0.42
6 Months	6 (20)	4 (13)	3 (10)	0.33
Long-Term	17 (57)	17 (57)	18 (60)	0.98

Values are mean ± SD and event rates are Kaplan-Meier estimates (number of events (%))